

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)


REC'D 19 APR 2005

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Applicant's or agent's file reference 12178312/VPA/sjp	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001624	International Filing Date (day/month/year) 3 December 2003	Priority Date (day/month/year) 3 December 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 14/47; G06F 17/00, 159:00		
Applicant THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 21 April 2004	Date of completion of the report 12 April 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  O.L. CHAI Telephone No. (02) 6283 2482

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001624

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 22-33, 54

because:

☐ the said international application, or the said claims Nos. 22-33 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 22-33, relating to a data store or a computer system with the data store, are considered to be mere representations of information and are therefore excluded subject matter for an international preliminary examination under Rule 67.1 (v).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 54

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001624

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 7-10, 12-15, 17-21, 34-53, 55	YES
	Claims 1-6, 11, 16	NO
Inventive step (IS)	Claims 9-10, 14-15, 34-53, 55	YES
	Claims 1-8, 11-13, 16-21	NO
Industrial applicability (IA)	Claims 1-21, 34-53, 55	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 WO 1997/035971
- D2 SWISS-PROT Accession No Q92843 01
- D3 GenPept Accession No BAB23468
- D4 GenPept Accession No AAH40369
- D5 GenPept Accession No BAB28740
- D6 The EMBO Journal vol 22 no 7 pp1497-1507, 2003
- D7 The Journal of Biological Chemistry vol 278 no 23 pp21124-21128, 2003.

D1 discloses human Bcl-w (SEQ ID No 7) and mouse Bcl-w (SEQ ID No 9) and the corresponding polynucleotides. SEQ ID No 7 has 98% identity with SEQ ID No 2 of the application, and SEQ ID No 9 has 95% identity. In their present wordings, claim 1 and appended claims are construed to include the known natural protein Bcl-w as the structure coordinates are inherent information of the molecule. Claims 1-6, 11 and 16 are therefore not novel or inventive in light of this disclosure. Further, claims 7-8, 12-13 and 17-21 are considered not inventive in light of the disclosure as these claims only involve routine manipulations by a person skilled in the art without having to exercise any inventive ingenuity.

D2 discloses an amino acid sequence of Bcl-w which anticipates claims 1-6, 11 and 16. Further, claims 7-8, 12-13 and 17-21 are considered not inventive in light of the disclosure as these claims only involve routine manipulations by a person skilled in the art without having to exercise any inventive ingenuity.

D3, D4 and D5 each discloses a Bcl2-like 2 peptide sequence which anticipates claims 1-6, 11 and 16. Further, claims 7-8, 12-13 and 17-21 are considered not inventive in light of the disclosure as these claims only involve routine manipulations by a person skilled in the art without having to exercise any inventive ingenuity.

D6 and D7 are published after the priority date of the application. As the application is entitled to its priority date, these documents are not relevant in the consideration of novelty or inventive step of the invention.

Claims 1-21, 34-53, 55 have industrial applicability.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 1-11 are not clear. These claims purport to define a "solution" of Bcl-w or its variants in terms of its structure coordinates. It appears that these claims are merely claims to a "solution" of Bcl-w or its variants and the structure coordinates are merely inherent information of the molecule. Prima facie, claims 1-6 encompass the known natural protein Bcl-w.
2. Claim 1 is not fully supported by the description. The term "comprises" is non-limiting and the claim therefore includes within its scope any Bcl-w or a variant that contains the active site as defined.
3. Claims 7-8 and 12-13 are not fully supported by the description. The Bcl-w variant claimed differs from the known natural occurring Bcl-w by deletion or substitution of one amino acid residue. There is no substantial support in the description for such broad claims.
4. Claim 16 is not clear. The term "consists essentially" is relative and it is therefore not clear what variations can be included in this claim.
5. Claims 17-21 are not fully supported by the description. The polypeptide encoding the Bcl-w variant claimed differs from the known natural occurring Bcl-w by deletion of one amino acid residue from the C-terminal. There is no substantial support in the description for such broad claims.
6. Claim 54 is not fully supported by the description. An agent or antagonist identified by a screening method of claims 34-53 is not a product made by a process. Prima facie, claim 54 may encompass compounds which are not novel. Further, there is no substantial support in the specification for such an agent.
7. The description is not clear. At page 12, paragraph [0042] refers to coloured amino acid residues in figure 2, but the figure on file is not coloured.